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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

L'ORÉAL S.A. and L'ORÉAL USA, INC.,	)	Civil Action No. 1:12-cv-00098-GMS
Plaintiffs,	)	JURY TRIAL DEMANDED
v.	)	**DECLARATION OF DR. SCAIANO IN SUPPORT OF DEFENDANTS JJCCI AND NEUTROGENA'S OPENING CLAIM CONSTRUCTION BRIEF**
JOHNSON & JOHNSON CONSUMER COMPANIES, INC. and NEUTROGENA CORPORATION,	)	
Defendants.	)	Filing Date: April 8, 2013. Hearing Date: June 10, 2013.

I, Juan Cesar ("Tito") Scaiano, Ph.D., hereby declare as follows:

I. BACKGROUND AND QUALIFICATIONS

1. I have been retained in the above-captioned litigation on behalf of Defendants Johnson & Johnson Consumer Companies, Inc. and Neutrogena Corporation (collectively, "Neutrogena").

2. I have been asked to provide expert testimony relating to the construction of claim terms in U.S. Patent Nos. 5,587,150 ("the '150 patent") and 5,576,354 ("the '354 patent") asserted by L'Oréal S.A. and L'Oréal USA, Inc. (collectively, "L'Oréal") in this litigation.[1] In particular, I have been asked to provide opinions regarding the meaning of the term "photostable . . . screening composition for protection of the human epidermis against ultraviolet rays of wavelengths between 280 and 380 nm" and the term "stabilizing . . . with respect to UV radiation of wavelengths between 280 and 380 nm." My opinions on these issues are set forth below.

3. I am currently the Canada Research Chair in Applied Photochemistry at the University of Ottawa, Canada, a position I have held since 2003. Between 2009 and 2012, I was the Chair of the Department of Chemistry. I have been a member of the faculty at the University of Ottawa since 1985. Prior to becoming Chair of the Department of Chemistry, I was a Professor of Chemistry from 1991 to 2000 and Adjunct Professor of Chemistry from 1985 to 1991. In 2000, I became Distinguished University Professor. My *curriculum vitae* is attached as Exhibit 1.

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[1] I understand that the '150 patent and the '354 patent share the same specification. For simplicity, the specification citations in this declaration will refer only to the '150 patent (the "'150 patent," APX0007–13), but they should be understood to include the corresponding portions of the '354 patent as well (the "'354 patent," APX0001–06).

4. I received my *Licenciado en Quimica* (equivalent to B.S. in Chemistry) from the University of Buenos Aires, Argentina, in 1967. In 1973, I received my *Doctor en Quimica* (equivalent to Ph.D. in Chemistry) from the University of Chile (work completed and defended in 1970). From 1970 to 1972 I completed a Postdoctoral Fellowship in the Department of Chemistry, University College, London, England. From 1972 to 1973, I was Assistant Professor, *Department de Quimica*, Universidad Tecnica del Estado, Santiago, Chile. From 1973 to 1975, I was Associate Professor, *Departamento de Quimica y Fisica*, Universidad Nacional de Rio Cuarto, Argentina.

5. From 1975 to 1976, I was Visiting Research Officer at the National Research Council ("NRC"), Division of Chemistry, Ottawa, Canada. From 1976 to 1979, I was Assistant Professional Specialist, Notre Dame Radiation Laboratory, University of Notre Dame, Notre Dame, Indiana. In 1979, I returned to the NRC, where I remained until 1991, holding the positions of Associate Research Officer (1979 to 1982), Senior Research Officer (1982 to 1987), and Principal Research Officer (1987 to 1991). From 1984 to 1991, I was Head of the Reaction Intermediates Group in the Division of Chemistry at the NRC.

6. I have expertise in the fields of photochemistry and physical organic chemistry. My research interests include, among other subjects, organic photochemistry, photocatalytic reaction mechanisms, sunscreens, laser-induced photochemistry, antioxidants, supramolecular systems, photocages, and sensors. I am an active participant in the Centre for Catalysis Research and Innovation (CCRI) at the University of Ottawa.

7. I have earned several academic awards related to my research in photochemistry and chemistry. Most recently I was awarded the Förster Medal by the Gesellschaft Deutscher Chemiker (GDCh) and the Deutsche Bunsen-Gesellschaft, and presented

in October 2012 in Potsdam Germany. I also received the Queen Elizabeth II Diamond Jubilee Medal for service to Canada, presented by the Governor General of Canada in June 2012. Other awards that I have received include induction as an Officer of the Order of Canada (2006); Premier's Platinum Research Excellence Award, Canada (2003) (which is Ontario's highest award in science and engineering and provides $1M in unrestricted research funds); Photon Award, American Society for Photobiology (2003); Honorary Fellow of the Golden Key International Honor Society (2003); and Gerhard Herzberg Canada Gold Medal for Science and Engineering (2002) ($1.25M in research support over 5 years). Additional awards and recognitions that I have received, including endowed lectureships, are listed in my *curriculum vitae*.

8. I have authored or co-authored approximately 630 scientific publications, two books, and several book chapters. In particular, I am Editor of the CRC "Handbook of Organic Photochemistry," Volumes I and II, published by CRC Press, Inc., Boca Raton, Florida, in October 1989. This text deals with equipment, materials, and techniques used in organic photochemistry; the properties of excited states; spectroscopy; and kinetics of reaction intermediates. In 2001, I was included in the top 100 most cited chemists. In addition, I have been listed as an inventor on five issued patents.

9. I served as Associate Editor of the journal *Photochemistry and Photobiology* for four years and as Editor-in-Chief between 1998 and 2003. *Photochemistry and Photobiology* is the official publication of the American Society for Photobiology. In my roles as Associate Editor and Editor-in-Chief, I reviewed hundreds of articles in the field of photochemistry, many of which were authored by those who develop and formulate sunscreens.

10. I have also served on the editorial boards of a number of other scientific publications, including *Journal of Photochemistry and Photobiology (A)* (1986 to present), *Accounts of Chemical Research* (1994 to 1996), *Research on Chemical Intermediates* (1994 to present), *Interscienta* (1996 to 1999), *International Journal of Chemical Kinetics* (1996 to present), and *Catalysis Science and Technology* (2012 to 2013). I am also a member of several scientific organizations and have served on a number of scientific committees.

11. In 1997, I founded Luzchem Research, a company that develops and manufactures specialized instrumentation for the study of the interaction of light with materials, including photostability chambers, xenon illuminators, solar simulators, spectroradiometers, laser flash photolysis equipment, thin film analyzers, and spectroscopy supplies. One of Luzchem's products is an instrument called "SolSim," a benchtop solar simulator that I designed.

12. My research group at the University of Ottawa consists of about fifteen researchers, including graduate and undergraduate students, several post-doctoral fellows, and frequent visitors from around the world. In addition, I have collaborations with many laboratories in Canada and around the world, including in Sweden, Brazil, and Spain.

13. In the course of my work in this matter, I have read a voluminous number of peer-reviewed scientific articles, written in the late 1980s into 1990, which discuss the photostability of avobenzone and other materials used in sunscreens, and have become well-versed in the terminology of how those in this field describe the stability of the chemical compositions being studied and the effects of sunlight and simulated sunlight on those compositions.

14. My opinions are based upon my own knowledge, education, and experience; review of the ’150 patent and the ’354 patent and their file histories, and relevant scientific literature, as discussed above.

15. I reserve the right to supplement or amend the opinions set forth in this Declaration based upon any additional documents and/or information I may receive, including information set forth in any Claim Construction submissions of L’Oréal.

II. ORDINARY MEANING OF THE CLAIM TERMS “PHOTOSTABLE . . .” AND “STABILIZING . . .” IN THE ’150 PATENT AND ’354 PATENT

A. Background on UV Radiation and Sunscreens

16. The sun emits energy over a broad spectrum of wavelengths, including ultraviolet (“UV”) radiation (wavelengths 100 to 400 nm). Scientists classify UV radiation into three types: UV A (wavelengths 320 to 400 nm); UV B (wavelengths 280 to 320 nm); and UV C (wavelengths 100 to 280 nm). Only UV A and UV B radiation reaches the earth’s surface.

17. The active ingredients present in sunscreens are usually organic or inorganic chemicals that absorb, reflect, and/or physically block the transmission of the sun’s UV rays to the skin. These active ingredients are commonly referred to as “UV filters” or sunscreen “agents.” Organic UV filters work by absorbing UV A and/or UV B radiation.

18. The concept of photostability relates to the tendency of a molecule to change or break down when exposed to electromagnetic radiation, such as ultraviolet (“UV”) radiation or visible light. Electromagnetic radiation is absorbed in units known as photons. UV filter molecules act by absorbing and dissipating energy transferred from photons of UV radiation. The way in which molecules interact with light is well understood: when a UV filter molecule absorbs a photon, it becomes “excited,” meaning that one or more electrons jump from a lower-energy orbital position to a higher-energy orbital position. Two common excited states that

result are the "singlet excited state" and the "triplet excited state." A UV filter molecule in the singlet excited state may dissipate its energy and return directly to the ground state, where it will be once again available to absorb another photon. Alternatively, a UV filter molecule in the singlet excited state may decay to the less stable "triplet excited state," and may undergo chemical reactions that cause it to change form, break apart, or react with other nearby molecules. This can cause UV filter molecules to degrade over time, which may have an effect on the absorbance and UV protective properties of a composition containing that UV filter.[2]

B. Photostability Testing

19. At the time the original application for the patents-in-suit was filed, the scientific literature discussed photostability in relative terms (for example, identifying which of two compounds was more or less photostable than the other) without providing any threshold (*i.e.*, a value below or above which photostability could be deemed present) for whether a particular compound was "photostable" or "stable." At that time, no accepted criteria, test methodology, or threshold value for determining photostability existed in the literature. On the contrary, a variety of criteria, test methods, and equipment were used for evaluating photostability, and no accepted criteria or test methodology existed in the art. For example, some researchers evaluated photostability by measuring the amount of an active ingredient (*e.g.*, avobenzone) that degraded after irradiation by UV rays for a period of time, whereas others measured the decrease in the sample's ability to block UV radiation after UV irradiation over time.

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[2] *See* Stewart Exh. 1, Turro, N. J., Modern Molecular Photochemistry; Benjamin/Cummings Publishing Co.: Menlo Park, 1978, at pp. 1–16; *see also* Stewart Exh. 2, Bonda, C., The Photostability of Organic Sunscreen Actives: A Review, in Sunscreens: Regulations and Commercial Development, 3d edition, N.A. Shaath ed., New York: Taylor & Francis Group, pp. 321–49 (2005), at pp. 323–26.

20. The criteria and test methodology for assessing photostability are important because the observed photostability of the same composition can vary significantly depending on the criteria and test methodology used. For example, if a given composition includes other screening compounds besides the one of interest, and those other screening compounds do not degrade but rather continue to provide UV screening, then the composition could be considered to show less photostability when tested for degradation of the active ingredient under study, but more photostability when tested for UV blocking characteristics. Alternatively, if a given composition includes other screening components besides the one of interest, and those other screening compounds do degrade (thereby altering the UV blocking properties of the composition), then the composition could be considered to show more photostability when tested for degradation of an active ingredient, but less photostability when tested for UV blocking characteristics.[3] This was true at the time the original application for the patents-in-suit was filed, and continues to be true today.

21. The absence of any generally accepted protocol for photostability testing was recognized in the scientific literature in the 1990 timeframe.[4] Indeed, the absence of any defined test conditions, criteria, and threshold value for photostability evaluation was recognized even long after the alleged inventions of the ’150 and ’354 patents were made, in a 1996 article co-authored by André Deflandre, one of the named inventors of the patents-in-suit. In this article,

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[3] The importance of properly selecting the photostability indicator is recognized in Stewart Exh. 3, Gonzenbach *et al.*, ‘Spectral Stability’ – a meaningful term?, *Int’l J. Cosmet. Sci.*, 9:287–92 (1988) (“Gonzenbach (1988)”) (describing examples in which differing photostability results are obtained depending upon the criteria used).

[4] *See* Stewart Exh. 4, Sperling-Vietmeier, K., UV filters for skin and product protection in cosmetic preparations, *Parfumerie und Kosmetic*, 71(3):172–78 (1990) (“Sperling-Vietmeier (1990)”), at p. 176 (“Another important demand made on a UV filter is its photostability, i.e. the UV filter should not break down even under intense radiation. This property is a matter at issue, but ***a generally accepted test method does not exist so far***.”) (emphasis added)).

Deflandre recognized that while accepted protocols are in use for photostability testing of industrial UV-absorbers, "the situation is quite different" for sunscreens. Deflandre also recognized there can be "a considerable difference" between photostability results attained using different test methods and criteria.[5]

C. Claim Language and Specification

22. The '150 and '354 patents describe and claim, among other things, "a photostable cosmetic composition" containing in combination a dibenzoylmethane derivative and an alkyl-β,β-diphenylacrylate or α-cyano-β,β-diphenylacrylate, and a "process for stabilizing" the dibenzoylmethane derivative with an alkyl-β,β-diphenylacrylate or α-cyano-β,β-diphenylacrylate derivative compound. *See* APX00008–09, '150 Patent, at Col. 1:10–17, Col. 1:48–63, Col. 3:1–8.

23. In my opinion, the asserted claims and written description of the '150 and '354 patents do not set forth any definition or otherwise provide any clear meaning for the terms "photostable . . . screening composition for protection of the human epidermis against ultraviolet rays of wavelengths between 280 and 380 nm" or "stabilizing . . . with respect to UV radiation of wavelengths between 280 and 380 nm." Rather, these terms are used as relative terms with no definitive boundary between compounds that can be so characterized and those that cannot.

24. The claims and specification merely use the term "photostable" (or "stabilizing") without providing a definition, test, criteria, or threshold for determining photostability. Indeed, the claims and specification do not include *any* testing or data to demonstrate the photostability of the claimed compositions, much less any test methodology,

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[5] *See* Stewart Exh. 5,Gonzenbach *et al.*, "Proposed protocol for determination of photostability Part 1: cosmetic UV filters," *Int'l J. of Cosmet. Sci.* 18(4):167–77 (1996), at pp. 168, 170–73, 176.

photostability indicator or criteria, threshold value, or standard for evaluating photostability. As a result, it is not possible to determine whether a given composition or process is within the scope of the claims.

25. The specification includes eight "Examples" of claimed compositions. These "Examples" describe various formulations that include avobenzone and octocrylene, including nonionic emulsions of avobenzone and octocrylene, formulations of sun oils, and oil-in-water emulsions. But these "Examples" do not involve any photostability or stability testing or, for that matter, testing of any kind. *See* APX0009–10, '150 Patent, at Col. 4:11–6:27.

26. The specification states that certain dibenzoylmethane derivatives "do not always possess sufficient photochemical stability to ensure constant protection during a prolonged exposure to the sun, which necessitates repeated applications at regular and frequent intervals if it is desired to obtain an effective protection of the skin against UV rays." APX0008, '150 Patent, at Col. 1:42–47. This general statement does not provide a meaningful definition because it does not explain how much protection must be achieved, how to measure that protection, or what test method or equipment should be used.

27. The specification also states that the inventors discovered that by combining certain dibenzoylmethane derivatives with other compositions (such as octocrylene) "in well-defined proportions and in a well-defined mole ratio, an exceptional photochemical stability of the dibenzoylmethane derivatives was surprisingly obtained." APX0008, '150 Patent, at Col. 1:61–63. This statement also does not provide a meaningful definition of "photostable," because it does not define what qualifies as a "photostable" or "stable" composition, and it does not explain how to determine whether a particular compound qualifies. It merely praises the alleged invention.

28. The specification also states that the invention imparts "a large sun protection factor as well as good persistence." APX0008, '150 Patent, at Col. 1:63–66. In this context, "persistence" is "defined as a small change in the protection factor after the subject who has received an application of the screening composition has bathed." APX0008, '150 Patent, at Col. 1:66–2:1. The property of persistence thus relates to how well the sunscreen stays on the skin, especially after exposure to water. It is unclear how this property would be helpful in determining photostability, and the specification does not provide an explanation.

D. Prosecution History

29. The prosecution histories of the '150 patent and '354 patent also do not set forth any definition or otherwise provide a clear meaning for the terms "photostable . . ." or "stabilizing . . . ." To the extent that the prosecution history sheds any light on the meaning of the term "photostable" or "stabilizing," it confirms that these terms are merely relative terms with no definitive boundary between compounds that can be so characterized and those that cannot. During prosecution, L'Oréal did not indicate how to determine whether a given composition or process is within the scope of the "photostability" and "stabilizing" terms in the claims of the '150 and '354 patents.

30. During prosecution of the '150 and '354 patents, applicants submitted a Declaration from inventor André Deflandre dated October 26, 1994 ("Deflandre Declaration") describing the results of photostability testing he had performed. *See* APX0141–45, '886 Appl., 11/9/94 Amdmt, Deflandre Decl. The Deflandre Declaration is the only submission by L'Oréal that contains any information concerning photostability testing in relation to the claimed inventions.

31. The Deflandre Declaration states that "the photostability of sunscreening compositions according to Serial No 07/937,886 was compared to the photostability of sunscreening compositions of GROLLIER," a prior art reference disclosing avobenzone. *Id.* at APX0142, p. 2. Four compositions were tested, Compositions 1 and 3 (which were said to contain avobenzone and octocrylene in weight percents and mole ratios as in the patent claims) and Compositions 2 and 4 (which were said to contain avobenzone and "Parsol MCX," a prior art UV-B filter[6]). The Deflandre Declaration reported that the claimed compositions showed a 10.6% and 18.2% loss of avobenzone and the prior art compositions showed a loss of 45.7% and 63% loss of avobenzone. Based on these results, Deflandre concluded that "the loss of [avobenzone] when combined with [octocrylene] in the claimed amounts and ratios is much lower, *i.e.*, 2.5 to 6 times lower than the loss of [avobenzone] combined with the prior art sunscreen PARSOL MCX in the same amounts and in the same ratios calculated with respect to [avobenzone]." *Id.* at APX0142–45, pp. 2–5.

32. Just as in the written description of the '150 and '354 patents, the Deflandre Declaration uses the terms "photostable" and "stabilizing" as relative terms. Indeed, the Deflandre Declaration does not say that compounds with greater degradation are not "photostable" or conclude that the claimed compositions are "photostable." Rather, the Deflandre declaration compares the relative photostabilities of different compositions.

33. The Deflandre Declaration also does not provide any threshold value for photostability or otherwise explain where to draw the line between a composition that is photostable and one that is not. Because all of the tested compositions degraded to some extent, the Deflandre Declaration indicates that in order to be "photostable" or "stabilizing," absolute

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[6] "Parsol MCX" is a trade name for octyl methoxycinnamate (2-ethylhexyl p-methoxycinnamate).

photostability is not required. The most that can be derived from the declaration is that the composition or process must inhibit degradation of avobenzone to some degree. However, even if one were to conclude that the claimed compositions were "photostable" and the prior art compositions were not, there is no indication of how to evaluate other compositions whose degradation falls in between.

34. Further, although the Deflandre Declaration states that "[t]he films were irradiated for 1 hour with the aid of a solar simulator," no information is provided concerning (a) the type of the solar simulator, lamps, and filters used; (b) the spectrum of the light delivered; (c) the intensity and dose of light delivered; or (d) how the samples were prepared. Without this information, it would not be possible to reliably replicate the tests set forth in the Deflandre Declaration.

E. L'Oréal's Proposed Construction

35. I understand that L'Oréal has proposed in this litigation that the claim term "photostable . . ." means "photochemical stability of avobenzone corresponding to the photochemical stability of avobenzone provided by 0.8 molar ratio of octocrylene to avobenzone in a neutral environment," and the claim term "stabilizing . . ." means "photochemically stabilizing avobenzone corresponding to the photochemical stability of avobenzone provided by 0.8 molar ratio of octocrylene to avobenzone in a neutral environment."

36. L'Oréal's proposed construction is not the ordinary or plain meaning of these terms, and I am not familiar with any publications or literature that use the terms in this manner. Nor do I believe that the patent claims, specification, or prosecution history provide either a special definition of this sort or support L'Oréal's definition. Indeed, they are inconsistent with L'Oréal's proposed definition.

37. L'Oréal defines "photostable" in terms of "photochemical stability." These terms, however, mean the same thing. Thus, L'Oréal's proposed construction is circular and does not clarify what is meant by "photostable . . ." or "stabilizing . . . ."

38. L'Oréal's proposed definitions are also limited to the combination of avobenzone with octocrylene. However, many of the claims of the patents-in-suit are not so limited, and recite the combination of dibenzoylmethane derivative and alkyl β,β-diphenylacrylate or α-cyano-β,β-diphenylacrylate derivatives. *See, e.g.*, APX0004–05, '354 patent, claims 1, 4, 5, 6, 14, 15; APX0008, APX0010–12, '150 patent, claims 1, 3, 4, 5, 16, 17, 18, 19, 20, Col. 1:10–17, Col. 1:48–2:50. Avobenzone and octocrylene are only one out of many possible pairs of active ingredients that would fall within the scope of the '150 and '354 patent claims that use the terms "photostable . . ." and "stabilizing . . . ." Thus, if L'Oréal's definition were applied consistently to all of the claims, it would make little sense and would be inconsistent with the usage of those terms in broader claims.

39. I also disagree with L'Oréal's proposed requirement that all compositions covered by the claims must have a photochemical stability "provided by 0.8 molar ratio of octocrylene to avobenzone," because the invention is not limited to a 0.8 molar ratio. Rather, the only limitation on the mole ratio is that it be "not less than 0.8," and compositions with higher mole ratios are specifically described in claims and tested as claimed compositions in the Deflandre declaration. *See* APX0009, APX0011–12, '150 Patent, claims 6, 23, Col. 3:7–9; APX0005–06, '354 patent, claims 3, 18; APX0143, Deflandre Decl., at p. 3. Compositions having different compounds or mole ratios (or both) can be expected to react differently when exposed to UV radiation, and there is no reason to expect that all such compounds covered by the claims will have a photostability "corresponding to the photochemical stability of avobenzone

provided by 0.8 molar ratio of octocrylene to avobenzone." And I see nothing in the intrinsic record that would indicate that all compounds covered by the claims would have such a photostability. I therefore do not agree with L'Oréal's proposed construction, which establishes a photostability benchmark based on a 0.8 molar ratio of octocrylene to avobenzone.

40. I further disagree with L'Oréal's proposed construction because it specifies a molar ratio of octocrylene to avobenzone, but fails to indicate the concentration (such as percent by weight) of either compound in the composition. The asserted claims encompass a variety of concentration values, and the photostability of avobenzone may change depending on its concentration, even if the molar ratio is fixed.

41. L'Oréal's proposed constructions also require a "neutral environment." The claims, specification, and file history of the '150 and '354 patents do not use this term or otherwise explain what it might mean or how to determine whether it is present. In chemistry, "neutral" is often used to refer to solutions in which the pH is neither acidic nor basic. But it is unclear whether L'Oréal's construction uses the term in this sense.

Dated: April 8, 2013

Juan C. Scaiano, Ph.D.